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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,053	02/19/2004	Jan Maria Rene Balzarini	TRIPEP.058A	6769

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EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/783,053	BALZARINI ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/19/04, 10/31/2005 and 11/13/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-109* is/are pending in the application.

4a) Of the above claim(s) *64 and 95-109* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62,63 and 65-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/26/04, 12/15/04+07/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the compound of formula (C) in the reply filed on 11/13/2006 is acknowledged.

Status of the claims

2. Claims 1-61 are cancelled. Claims 62-109 are added. Claims 64 and 95-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2006.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the distinction among the various variables cited in the legend. The Office directs Applicant's attention to Figures 7-8 and 10-13, which are bar graphs of various experiments. In the cited figures, the bar graphs contain a legend that is directed at differentiating among the various experiments. However, because the legend, as presented to the Office, is in black and white form, the Office cannot readily distinguish the difference among the variables. For example, as shown, the legend of Figure 10 provides that the same darkened bars are directed to experiments conducted at 24 **and** 48 hours. In the case of Figure 10, a distinction between the two experiments cannot readily be made. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office

action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

4. The information disclosure statement filed 07/26/2004 has been considered in part. Specifically, items 66-67, 82, 104, 112, 120 and 126 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because:

37 C.F.R. § 1.98 (b5) provides: Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

In the instant case, the cited items do not comply with 37 C.F.R. § 1.98 (b5) because the cited items do not include a title for the cited publication. The publications

itself has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 63 and 80-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63, which claims 80-94 depend, limits the alpha hydroxyglycinamide to a compound of formula (C). However, claim 63 does not set forth the parameters or structural element that is encompassed by formula (C). In the absence of any of such guidelines, it is unclear what Applicant intends to encompass by formula (C). Thus, the claim is rejected under 112, 2nd paragraph for failing to particularly pointing out and distinctly claiming the subject matter. In the instant case, the subject matter is the metes and bounds of formula (C). The instant rejection also affects claims 80-94 because the cited claims recite a dependency to claim 63.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 62-63 and 65-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting replication of HIV *in vitro* comprising providing an effective amount of alpha hydroxyglycinamide or a pharmaceutically acceptable salt thereof to a cell culture. However, the specification does not reasonably provide enablement for a method of inhibiting replication of HIV comprising providing a therapeutically effective amount of alpha hydroxyglycinamide or a pharmaceutically acceptable salt of alpha hydroxyglycinamide in a subject thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Nature of the invention:

The claims are directed to the use of a metabolite of known prodrug GPG-NH_2, a tripeptide, to inhibit the replication of human immunodeficiency virus HIV. The claims limit the metabolite to alpha-hydroxy-glycine-amide (alpha-hydroxyglycinamide, alphaHGA).

Breadth of the claims:

As provided in the claims, the claimed invention is directed at the inhibition of HIV in a subject in need thereof.

In the instant case, to better understand the full breadth of the claims, the Office turned to Applicant's specification. It is noted that the specification provides that additional embodiments of the claimed invention include approaches to treat and/or prevent HIV infection. [4th sentence, first paragraph, page 8.] The same disclosure is noted on page 48 of the specification, which teaches, "these compounds can be formulated into a medicament or pharmaceutical, which can be used to inhibit HIV replication and treat and/or prevent HIV infection:" Page 81 of the specification further provides that the compounds "is also suitable for use in situations where prevention of HIV infection is important" and that the compounds "can be formulated into antiviral compositions for sue during sexual intercourse so as to prevent transmission of HIV." Hence, in view of the disclosure, it is found that the full breadth of the claims

encompasses inhibiting HIV replication, treating HIV infection, and preventing HIV infection. It should be noted that the claims are not limited to an *in vitro* use.

Absence or presence of working examples:

The specification teaches how to enzymatically prepare and synthetically prepare alpha-hydroxyglycinamide. The specification also teaches that alpha-hydroxyglycinamide inhibit the replication of HIV in vitro. Hence, the specification is enabling for a method of inhibiting replication of HIV *in vitro* comprising providing an effective amount of alpha hydroxyglycinamide or a pharmaceutically acceptable salt thereof to a cell culture.

However, the specification does not contain any working examples demonstrating the effectiveness of the *in vitro* observations *in vivo*.

Amount of guidance of direction provided:

As provided above, the specification teaches how to enzymatically prepare and synthetically prepare alpha-hydroxyglycinamide, and that alpha-hydroxyglycinamide inhibit the replication of HIV *in vitro*. Besides these teachings, the specification does not contain any additional guidance or direction. The specification does not set forth any guidance relating the *in vitro* data with an *in vivo* efficacy, nor does the specification set forth any guidance or direction showing that alpha-hydroxyglycinamide is effective at inhibiting HIV *in vivo*. In the instant case, the disclosure in the specification does not contain sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and

without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

State of the art:

It is well known in the art that retroviral infections in general, and HIV infections in particular, are refractory to anti-viral therapies. The obstacles to HIV/AIDS therapy and vaccine formulations are well documented in the literature. The obstacles includes: i) the inability current vaccine designs to elicit effective neutralizing antibodies against circulating strains of HIV;[1, 2] ii) the inability of current vaccine designs to prevent HIV from establishing persistent infection; [3] iii) the extensive global variability of HIV;[4, 5, 6, 7] iv) the lack of understanding regarding the mechanisms of protection;[8,9] v) the lack of understanding of which HIV antigens induce protective immunity and which immune effector mechanisms are responsible for protection;[10]vi) lack of immune correlates;[11, 12, 13, 14] vii) it is unknown if strong immune responses at mucosal surfaces will be necessary to

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[1] Klausner et al. The need for a global HIV vaccine enterprise. Science, Vol. 300, June 2003, pp. 2036-2039, see underlined text.
[2] Desrosiers, Prospects for an AIDS vaccine. Nature Medicine, Vol. 10(3), March 2004, pp. 221-223, see underlined text.
[3] Ibid.
[4] Ibid.
[5] Desrosiers, opt. cit.
[6] Lee. Chapter 32 AIDS Vaccines: 32.1 Acquired immunodeficiency disease vaccines: design and development. AIDS: Biology, Diagnosis, Treatment, and Prevention, fourth edition, edited by DeVita, Jr. et al., Lippincott-Raven, 1997, pp. 605-616, see underlined text on page 609.
[7] Bende, et al. Update: Search for an AIDS vaccine. AIDS Read, 10(9), 2000, pp. 526-537, see Table 3.
[8] Klausner, op. cit.
[9] Desrosiers, op. cit
[10] Ibid.
[11] Nabel, op. cit.
[12] Beyrer, The HIV/AIDS vaccine research effort: An update. The Johns Hopkins University AIDS Service, The Hopkins HIV Report, Vol. 15 (1), January 2003, pp. 1-16, see pp. 6-7 and underlined text.
[13] Lee, op. cit., p. 608.

provide protection from sexual transmission;[15] viii) inability to identify immunogens that induce broad and long lasting immunity;[16] and ix) lack of a practical animal model system for HIV. [17, 18,19,20, 21].

The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the instantly claimed invention with a reasonable expectation of success and without undue experimentation.

Furthermore, Applicant has not provided any convincing evidence that alpha hydroxyglycinamide is indeed therapeutic against HIV infection. There is no working example that is drawn to the administration of alpha hydroxyglycinamide to treat or prevent HIV infection.

The predictability or unpredictability of the art:

In the instant case, since it's discovery, the eradication of HIV-1 from an infected individual has proven elusive to the scientific community. The art clearly demonstrates that the discovery of HIV treatment and vaccines has been far from being a trivial endeavor and that the path to finding a vaccine for treating HIV and for HIV treatment is full of unpredictability. For example, in the absence of a practical animal model system for the virus and immune correlates, the efficacy of a candidate treatment protocol cannot readily be predicted.

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[14] Bende, op. cit.
[15] Ibid.
[16] Nable, op. cit.
[17] Feinberg et al. AIDS vaccine models: challenging challenge viruses. Nature Medicine, Vol 8 (3), March 2002, pp 207-210, see underlined text.
[18] Nabel, op. cit.
[19] Beyrer, op. cit.
[20] Lee, op. cit., p. 609.
[21] Bende, op. cit.

Quantity of experimentation necessary:

In view of the teachings that provided in the specification, which is solely limited to in vitro use of alpha-hydroxyglycinamide to inhibit HIV replication, and the art, it can be clearly established that the skilled artisan would not be able to practice the claimed invention without an undue burden of experimentation. In order to practice the claimed invention, the skilled artisan would have to establish a practical animal model system for HIV, discover and understand the protective mechanism, discover the type of immune activation necessary to render treatment and prevention of HIV in a subject. In the instant case, the imposition of such experimentation, which is beyond routine experimentation, on the skilled artisan would necessarily be undue. It should further be noted that Applicant has not shown or taught the skilled artisan how to overcome any of these obstacles. Hence, the skilled artisan would not be able to turn to Applicant's disclosure for any relief. Therefore, in view of the analysis provided above, it is found that the instant specification is not enabling for the full scope of the claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 62-63 and 65-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-22 and 28-33

of copending Application No. 11/409671. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim of the instant patent application is claim 62, which is directed to a method of inhibiting the replication of HIV comprising providing a therapeutically effective amount of alpha-hydroxyglycinamide or a pharmaceutically acceptable salt thereof to a subject in need thereof.

The broadest claim of the conflicting patent application is claim 20, which is directed at a method of inhibiting the replication of HIV comprising providing a therapeutically effective amount of a compound of formula (B) or a pharmaceutically acceptable salt thereof to a subject in need thereof.

The difference between the claim sets is: claim 20 of the conflicting patent is directed at a compound of formula (B), whereas, claim 62 of the instant patent application is specifically directed to alpha-hydroxyglycinamide. However, upon inspection of claim 20 of the conflicting patent, it is noted that one of the compound encompassed by formula (B) is alpha-hydroxyglycinamide. This is further evidenced by claims 21-22 of the conflicting patent application. Claim 21 teaches alpha-hydroxyglycinamide, and claim 22 teaches a pharmaceutical salt of alpha-hydroxyglycinamide. In the instant case, the conflicting claims teach the claimed invention. Hence, the claims of the conflicting patent application anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 62-63 and 65-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-12 of copending Application No. 11/410633. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim of the instant patent application is claim 62, which is directed to a method of inhibiting the replication of HIV comprising providing a therapeutically effective amount of alpha-hydroxyglycinamide or a pharmaceutically acceptable salt thereof to a subject in need thereof.

The broadest claim of the conflicting patent application is claim 2, which is directed at a method of inhibiting the replication of HIV comprising a) identifying a subject in need of a compound that is inhibits HIV replication, b) providing a therapeutically effective amount of a compound of formula (N) or a pharmaceutically acceptable salt thereof to a subject in need thereof, and c) measuring the inhibition of replication of HIV in said subject.

The difference between the claim sets is: claim 2 of the conflicting patent is directed at a compound of formula (N), whereas, claim 62 of the instant patent application is specifically directed to alpha-hydroxyglycinamide. However, upon inspection of claim 2 of the conflicting patent, it is noted that one of the compound encompassed by formula (N) is alpha-hydroxyglycinamide.

The other difference between the claim sets is: claim 2 of the conflicting patent application requires the step of identifying a subject in need of a compound that is inhibits HIV replication and measuring the inhibition of replication of HIV in said subject;

whereas, claim 62 of the instant patent application does not recite the cited steps. However, it should be noted that claim 62 of the instant patent application recites the transitional term "comprising", which provides for the addition of additional ingredients or steps. In the instant case, the method of claim 2 of the conflicting patent is a species of the method recited in claim 62 of the instant patent application. Hence, claim 2 of the conflicting patent application anticipates claim 62 of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 62-63 and 65-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-67 and 69-70 of copending Application No. 10/920831. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim of the instant patent application is claim 62, which is directed to a method of inhibiting the replication of HIV comprising providing a therapeutically effective amount of alpha-hydroxyglycinamide or a pharmaceutically acceptable salt thereof to a subject in need thereof.

The broadest claim of the conflicting patent application is claim 63, which is directed at a method of inhibiting the replication of HIV comprising providing a therapeutically effective amount of a compound of the formula recited in the claim or a pharmaceutically acceptable salt thereof to a subject in need thereof.

The difference between the claim sets is: claim 63 of the conflicting patent is directed at a compound of the formula recited in the claim, whereas, claim 62 of the

instant patent application is specifically directed to alpha-hydroxyglycinamide. However, upon inspection of claim 63 of the conflicting patent, it is noted that one of the compound encompassed by formula recited in the claim is alpha-hydroxyglycinamide. In the instant case, the conflicting claims teach the claimed invention. Hence, the claims of the conflicting patent application anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M. Le 1/19/07
Emily M. Le
Patent Examiner
Art Unit 1648

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